A RATE ADAPTIVE DEMAND PACEMAKER

BACKGROUND OF THE INVENTION

1.   Field of the Invention - The present
invention relates generally to medical devices, and more
5   specifically relates to implantable electronic devices for
muscle stimulation.

2.   Description of the Prior Art - The earliest
implantable pacing systems operate asynchronously to
normal physiologic functions. U.S. Patent No. 3,057,356,
10   issued to Greatbatch, teaches such a pacer which has a
fixed rate oscillator coupled to an output driver circuit.
Each cycle of the fixed rate oscillator causes generation
of a stimulating pulse by the output driver circuit.
Designs soon incorporated the demand feature which senses
15   natural electrical activity in the heart and generates a
stimulating pulse only if none is provided physiologically
within a fixed escapement period. Demand mode pacers are
now the most popular and probably outnumber all other
types combined. Even though later improvements provide
20   programmability of the escape interval, the effective
pacing rate of such demand pacers is non-responsive to
changes in physiological requirements.

There has been considerable work done in the area
of physiologically controlled pacers. Most of these
25   devices measure some parameter and adjust the period of
the oscillator in response to changes therein. An early
such device is taught by Cohen in U.S. Patent No.
3,358,690. In this special case, however, the physiologic
parameter measured is instantaneous blood pressure within
30   the right atrium. This system will apparently work well
for patients having complete atrial ventricular block with
properly paced atria. The Cohen approach is not likely to
be effective for sick sinus syndrome, sinus/atrial block,
or similar disorders.

Later physiologically controlled pacer systems have been developed which have more general application and may be categorized by the parameter measured. Krasner et al in U.S. Patent No. 3,593,718 teaches sensing of
5 mechanical activity within the thorax. It is assumed that changes in respiration rate are thereby sensed. The oscillator of the pacing system has its rate controlled by changes in this parameter. Dahl, in U.S. Patent No. 4,140,132 teaches an improved implantable sensor for
10 determining level of a patient's physical activity for rate-controlling a pacer as taught by Krasner et al.

Bozal Gonzalez in U.S. Patent No. 4,201,219 teaches rate control of a pacer based upon neurological activity. Electrodes imbedded in the nervous system sense
15 electrical activity. Somehow, the amount of this electrical activity is used to control the oscillator rate of an asynchronous pacer.

By far the most promising techniques appear to involve the sensing of certain chemical parameters of
20 venous, often intracardiac blood. Alcidi in U.S. Patent No. 4,009,721 teaches a pacer controlled by the pH of the blood. A chronically implantable sensor determines the blood pH. The rate of an oscillator of an asynchronous pacer is controlled by the sensed pH. It has been shown
25 that blood pH decreases during prolonged muscular exercise. Mauer et al in U.S. Patent No. 4,252,124 teach an improved pH sensor.

Wirtzfeld et al in U.S. Patent No. 4,202,339 teach a pacing system having the rate of an asynchronous
30 oscillator controlled by the O_2 level of the intracardiac venous blood. As with all known prior art, physiologically controlled pacers, Wirtzfeld et al teach what is essentially an asychronous pacer as described by the above identified patent issued to Greatbatch, with an
35 oscillator rate directly controlled by the measured parameter. As such, these devices are less than optimal for treating cases of partial heart block.

SUMMARY OF THE INVENTION

The present invention employs demand mode pacing
with an escape interval that is determined by a measured
physiological parameter. This results in a pacer system
5 which can intermittently pace, upon demand, in hearts with
partial block or sick sinus syndrome at a minimum rate
that varies with physiological requirements. The
preferred mode senses level of molecular oxygen within
intracardiac venous blood. As the oxygen level decreases,
10 the escape interval is shortened thus providing a higher
minimum rate. Similarly, an increase in oxygen level
causes a lengthened escape interval. Notice that, unlike
prior art physiologically controlled pacers, the present
invention treats partial heart block or sick sinus
15 syndrome in the demand mode.

The present invention may be readily employed
with sensors which measure other parameters, such as pH of
blood, respiration rate. etc. Also, the present invention
is readily utilized in both single chamber and two-chamber
20 pacing modes.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of a typical prior
art physiologically controlled pacing system.

FIG. 2 is a schematic diagram of a single chamber
25 pacing system employing the present invention.

FIG. 3 is a schematic diagram of Demand Logic
106.

FIG. 4 is a schematic diagram of Sensor
Processing 30.

30 FIG. 5 is a schematic diagram of the dual-chamber
pacing system employing the present invention.

FIG. 6a is a table relating shift register
position and corresponding minimum heart rate.

FIG. 6b is a table relating oxygen level to
35 escape interval.

DETAILED DESCIPTION OF THE PREFERRED EMBODIMENTS

     The present invention is described herein in relation to the preferred modes of single and two-chamber pacing systems employing sensors measuring molecular oxy-

5   gen level in intracardiac venous blood. Those of skill in the art, however, will be readily able to apply these teachings to devices using other pacing modes and measuring other physiologic parameters.

     FIG. 1 is a schematic diagram of a typical prior

10 art physiologically controlled pacing system. Sensor 12 is located within right ventricle 20 of heart 10. Sensor 12 may measure molecular oxygen level in the intracardiac blood as taught by Wirtzfeld et al, for example. Line 14 transmits the output of Sensor 12 to Sensor processing 30

15 of pulse generator 24. Sensor processing 30 transforms the sensed signal into a signal for controlling the rate of variable rate oscillator 28 via line 32. The output of variable rate oscillator 28 is thus a train of pulses having an interpulse period determined by the sensed param-

20 eter. Driver 26 amplifies this pulse train which is transferred to stimulating electrode 18 via conductor 16. Thus, right ventricle 20 is stimulated asynchronously of atrium 22 at a rate determined by the level of oxygen sensed by Sensor 12.

25   FIG. 2 is a schematic diagram of a single chamber pacing system employing the present invention. The system employs a prior art sensor 12 located within right ventricle 20 of heart 10. A probe for measuring oxygen level as disclosed in the Wirtzfeld et al patent is preferable.

30 However, the reader should acquaint himself with the papers: "A Miniature Fiber Optic pH Sensor Suitable for In-Vivo Application," by Goldstein et al of the National Institute of Health and "Fiber Optic pH Probe for Physiological Use," Analytical Chemistry, Vol. 52, pp 864-869

35 (1980) by Peterson et al. Though these papers describe devices for measuring the less desirable parameter of pH, the technique of indirect measurement they propose seems

promising for chronically implantable oximetry sensors as well. Sensor processing 30 converts the analog signal received from sensor 12 via line 14 into digital form and transfers a digital escape interval control signal to
5 demand logic 106 via line 32.

Line 104 transfers an intracardiac EKG signal from right ventricle 20 to sense amp 102. The operation of sense amp 102 is common in the art. Its purpose is to examine the intracardiac EKG signal received via line 104
10 and determine when a QRS complex of natural origin is sensed. The output of sense amp 102 via line 108 signifies that no artificial stimulation pulse should be generated for at least one complete escape interval, since a naturally paced contraction has just occurred. U.S.
15 Patent No. 3,478,746 issued to Greatbatch teaches the function and operation of such a sense amplifier.

Fixed rate oscillator 112 serves as an internal clock for demand logic 106. A rate of 60 hertz is chosen as sufficiently fast and yet conserving of power. Fixed
20 rate oscillator 112 supplies a 60 hertz pulse train to demand logic 106 via line 110.

Demand logic 106 counts an escape interval having a period established by sensor processing 30 in multiples of 1/60 second. If a pulse is not received from sense amp
25 102 via line 108 during that escape interval, demand logic 106 transfers a pulse enable signal to driver 26 via line 34. If a pulse is received from sense amp 102, a naturally paced contraction has occurred and the escape interval is reset without transferring a pulse enable signal to
30 driver 26 via line 34. The important feature is that the escape interval is not fixed but is a period determined by the signal received from sensor processing 30 via line 32 which is indicative of the current oxygen level in the intracardiac blood.
35 Driver 26 receives the pulse enable signal from demand logic 106 via line 34 and produces a stimulation pulse which is transferred to the tissue of right

ventricle 20 by conductor 16 and electrode 18. Driver 26
is preferably a capacitive discharge circuit common in the
art. The design of such a circuit may be found in
commonly assigned U.S. Patent No. 4,276,883 issued to
5 McDonald et al.

FIG. 3 is a detailed schematic diagram of demand
logic 106. The function of demand logic 106 is to count a
period of time equivalent to the escape interval for the
current level of oxygen in the intracardiac blood and
10 generate a pulse enable signal if and only if no QRS
complex was detected during that escape interval. Upon
generation of a pulse enable or receipt of a QRS complex
detection signal, the escape interval is reset to zero.

The clock signal is a 60 hertz pulse train
15 received from fixed rate oscillator 112 via line 110 as
explained above. The clock signal serves to sequence 30
bit shift register 156 and 38 bit shift register 158.
These are constructed from common CMOS monolithic part
types.

20 OR gate 150 outputs a start reset signal whenever
a QRS detect signal is received from sense amp 102 via
line 108 or a pulse enable signal is generated and
transmitted to OR gate 150 via line 34a. One-shot 152,
being a common part type forms the start reset signal into
25 a clear signal suitable for clearing 30 bit shift register
156 and 38 bit shift register 158. The output of one-shot
152 supplies the clear signal via lines 168a and 168b to
30 bit shift register 156 and 38 bit shift register 158,
respectively.

30 The clear signal generated by one-shot 152 is
also transferred to delay 154 which delays the pulse
sufficiently long to enable 30 bit shift register 156 and
38 bit shift register 158 to be cleared. The pulse width
of the clear signal is a sufficient delay time. The
35 output of delay 154 is transferred via line 170 to set the
least significant bit (LSB) position of 30 bit shift
register 156. The result is that 30 bit shift register

156 and 38 bit shift register 158 are both cleared at the occurrence of a sensed QRS complex or the generation of a stimulating pulse. The LSB is next set and shifted one bit position at each pulse of the clock signal (i.e., at

5 60 hertz). It is easily seen that the LSB requires 500 milliseconds to shift to the carry output of 30 bit shift register 156 from whence it is propogated via line 166 to the LSB position of 38 bit shift register 158. Again, it requires 1/60 second to shift to each succeeding bit

10 position of 38 bit shift register 158.

It would take an additional 633 milliseconds for the set bit to shift the entire length of 38 bit shift register 158. This provides a total time of 1.133 seconds to shift the entire combined length of 30 bit shift

15 register 156 and 38 bit shift register 158. The maximum escape interval for the system is therefore 1.133 seconds, which corresponds to a heart rate of 52.9 beats per minute.

The output of each of the 38 bit positions of 38

20 bit shift register 158 is supplied via cable 164 to 38 x 1 MUX 162. By selecting the desired one of the 38 bit positions any one of 38 different escape intervals may be provided between 500 milliseconds (corresponding to 120 beats per minute) and 1.133 milliseconds (corresponding to

25 52.9 beats per minutes) in 1/60 second intervals. Of course, the rate of the clock signal may be increased to achieve greater resolution if required. Similarly, the length of 38 bit shift register 158 may be changed and/or the length of 30 bit shift register 156 changed to change

30 the range of selectable escape intervals.

Common monolithic CMOS parts are used to fabricate 38 x 1 MUX 162. A six bit input received from six bit latch 160 via line 161 selects one of the 38 bit positions of 38 bit shift register 158 and thus determines

35 the escape interval. If the LSB entered into 30 bit shift register 156 reaches the selected one of the 38 bit positions of 38 bit shift register 158, 38 x 1 MUX 162

outputs the pulse enable signal via line 34. Referring
again to FIG. 2, it is seen that this results in the
output of a stimulating pulse by driver 26. To ensure a
minimum rate based upon the maximum escape interval, the
5 carry output of 38 bit shift register 158 may be "ORED"
with line 34. This is an optional safety measure.

Referring again to FIG. 3, selection by 38 x 1
MUX 162 is made by the six bit contents of six bit latch
160 which simply holds the current escape interval
10 selector as received from sensor processing 30. A single
common monolithic CMOS part is available to implement
six bit latch 160.

Two control signals are required by six bit latch
160 as received by cable 32a. A first one of these
15 signals clears the contents of six bit latch 160 and a
second one is delayed and enables the six bit quantity on
cable 32b to be latched into six bit latch 160.

FIG. 4 is a detailed schematic view of sensor
processing 30. The analog sensor information is received
20 from sensor 12 via line 14. As in Wirtzfeld et al, this
is simply a signal having a voltage that is proportional
to the percentage of concentration of molecular oxygen in
the intracardiac venous blood. Amp 172 processes the
analog signal and scales it for input to six bit A/D 176
25 via line 182. The processed analog signal is converted by
six bit A/D 176 into a digital signal which is transmitted
via cable 32b to six bit latch 160. The data ready output
signal is supplied via one conductor of cable 32a to clear
six bit latch 160. The data ready signal is delayed by
30 delay 178 and sent via the other conductor of cable 32a to
enable the six bit data into six bit latch 160. Clock 174
supplies the convert signal to six bit A/D 176. Clock 174
may have a very low rate (i.e., a fraction of one hertz)
as the measurable changes in blood oxygen level occur
35 slowly relative to the conversion time of six bit A/D 176
and the resulting escape interval. Fixed rate oscillator
112 or a submultiple thereof may be substituted for clock

174, but the asynchrony of a separate clock 174 is probably not detrimental and requires fewer components.

   FIG. 5 is an alternate embodiment of the present invention as incorporated in a two-chamber pacing system.
5 The elements of sensor processing 30, sensor 12, electrode 18, demand logic 106 and fixed rate oscillator 112 are identical to the corresponding elements of the single chamber system and function as discussed above. Driver (v) 26 is also identical to the driver 26 of the single
10 chamber system.

   Sense amp 102 of the single chamber system is replaced by sense amp (p) 102a which is coupled via line 104a to an electrode in atrium 22. In this way sense amp 102a monitors the atrial activity rather than the ventric-
15 ular activity monitored by sense amp 102 in the single chamber system (see also FIG. 2). Therefore, sense amp 102a (p) generates a p-wave sensed signal which is transferred to demand logic 106 via line 108, whenever atrium 22 is naturally paced. Sense amp (p) 102a is similar to
20 sense amp 102 except for the enhanced sensitivity as is commmonly known in the art for p-wave sense amplifiers.

   As with the single chamber system, demand logic 106 generates a pulse enable circuit whenever the escape interval period has been reached as explained above. How-
25 ever, in this embodiment, the escape interval is measured between p-waves rather than between r-waves. Therefore a delay is supplied by A-V delay 202 to simulate the normal atrial-to-ventricular propogation delay. This may be a fixed delay which is easily accomplished or may be a delay
30 which is related to the pacing rate (i.e., the inverse of the escape interval) as is also known in the art.

   Atrium 22 may also be artificially stimulated using driver (A) 204 and conductor 206. This option provides an effective therapy for combined intermittent
35 sinus-atrial block, sick sinus syndrome, sinus bradycardia, and atrial-ventricular block. The

optional driver (A) 204 improves hemodynamic performance by stimulating a synchronized atrial kick.

Other configurations can be readily constructed using the teachings found herein. For example, driver (V)

5 26 may be deleted with only driver (A) 204 in use. This configuration would readily treat intermittent sinus-atrial block or sick sinus syndrome in a patient having normal atrial-ventricular conduction.

FIG. 6a is a table showing the effective minimum

10 heart rate in beats per minute corresponding to various selected bit positions of 30 bit shift register 156 and 38 bit shift register 158 (with the total cumulative number of bit positions shown). The maximum number of bit positions permitted by the embodiment of demand logic 106

15 shown in FIG. 3 is 68. However, the table of FIG. 6a is extended to 78 bit positions to show the effect of extending 38 bit shift register 158 to 48 bits.

FIG. 6b shows the relationship between a given level of molecular oxygen in the intracardiac venous

20 blood and the output required of six bit A/D 176 to six bit latch 160. This result is obtained by adjusting the bias of amp 172 to provide a zero voltage input to six bit A/D 176 for an oxygen level of 60% of saturation. The gain of amp 172 is adjusted to drive six bit A/D 176 to

25 approximately one-half of its maximum value for an oxygen level of 70% of saturation. As can be seen, therefore, a five bit A/D conversion is sufficient for the chosen system resolution. However, six bit devices are more commonly available. The total measured range of interest

30 in oxygen level is between 60% and 70%. Because of the components chosen, this provides an escape interval range corresponding to 52.9 to 120 beats per minute. The system is self-limiting to remain within this range. The ideal relationship of saturation levels to escape interval can

35 vary from patient to patient, and is preferrably programmable using an external device. Support may be

'readily found in the current literature to permit
determination of other effective relationships.
What is claimed is: